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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	1999/0795
Date of Filing	24 September 1999
Applicant	GAYA LIMITED, an Irish company of 2-3 Sandyford Village, Sandyford, Dublin 18, Ireland.

Dated this 9 day of March 2004.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

Request for the Grant of a Patent

990795

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☒ the grant of a patent under Part II of the Act

☐ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder

1. Applicant(s)

Name GAYA LIMITED

Address 2-3 Sandyford Village,
Sandyford,
Dublin 18
Ireland

Description/Nationality an Irish company

2. Title of Invention HAND ACCESS PORT DEVICE

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

<u>Previous Filing Date</u>	<u>Country in or for which Filed</u>	<u>Filing No.</u>
30 th July 1999	Ireland	S990660
.....
.....

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the Inventor(s)

.....

Address

.....

5. **Statement of right to be granted a patent (Section 17(2)(b))**

.....
.....

6. **Items accompanying this Request - tick as appropriate**

- (i) ☒ prescribed filing fee (£100.00)
- (ii) ☒ specification containing a description and claims
☐ specification containing a description only
☒ drawings referred to in description or claims
- (iii) ☐ an abstract
- (iv) ☒ copy of previous application(s) whose priority is claimed
- (v) ☐ translation of previous application whose priority is claimed
- (vi) ☒ Authorisation of Agent (this may be given at 8 if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**

The following information is applicable to the present application which is made under Section 24:-

Earlier Application No. Filing Date

8. **Agent**

The following is authorised to act as agent in all proceedings connection with the obtaining of a patent to which this request relates and in relation to any patent granted:-

MACLACHLAN & DONALDSON, 47 Merrion Square, Dublin 2

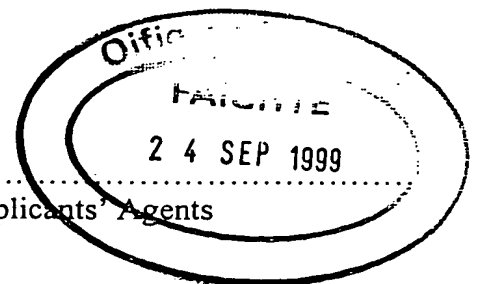
9. **Address for Service (if different to that at 8)**

MACLACHLAN & DONALDSON, at their address as recorded for the time being in the Register of Patent Agents (Rule 92)

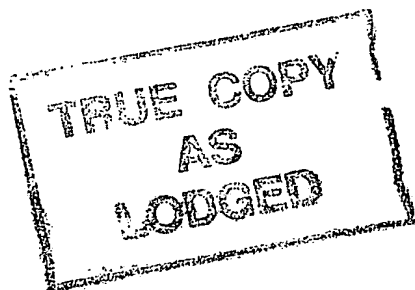
Signed Name(s) **GAYA LIMITED**

By

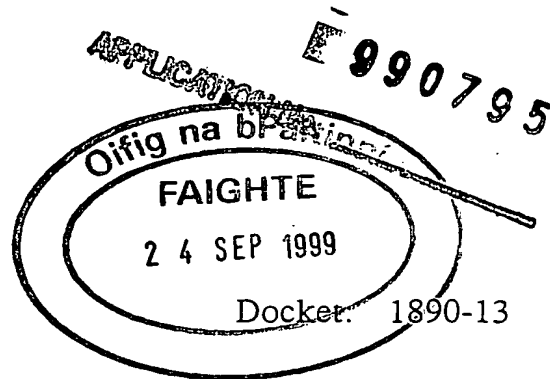
[Signature]
MACLACHLAN & DONALDSON, Applicants' Agents



Date 24th September 1999



- 1 -



HAND ACCESS PORT DEVICE

BACKGROUND OF THE INVENTION

Technical Field

5 The present invention relates to an improved hand access port which enables hand access during laproscopic surgery while retaining pneumoperitoneum.

Description of the Related Art

10 Minimally invasive surgery is surgery carried out by causing a minimum amount of trauma by incision in a patient's body. This type of surgery almost invariably involves deliberately introducing gas into a patient's peritoneal cavity to cause pneumoperitoneum.

15 Accordingly, surgical sleeves have been developed to prevent gas from escaping from the patient's body cavity while allowing the surgeon to operate using minimally invasive surgery techniques. These sleeves create a controlled pressurized environment within the sleeve while allowing the surgeon's arm to pass through the sleeve. For example, U.S. Patent Nos. 5,803,921 and 5,899,208 both disclose an access port device having an inner sleeve, an outer sleeve, an exit opening sealing feature for preventing substantial leakage of gas from the patient's body in the region of an exit opening and an entry opening

sealing feature substantially preventing gas leakage around the surgeon's arm at the entry opening. A lower annular edge of the outer sleeve is sealingly secured, for example by adhesive, either to wrapping material applied to the patient or directly to the patient's skin. The exit opening sealing feature
5 includes a pair of arcuate bands positioned to bring the opposing faces of the sleeve into contact to form an initial seal. The arcuate bands are passed through the incision into the abdomen. During pressurization, the arcuate bands also function to prevent the tendency of the inner sleeve to invert under pressure since the bands cannot pass back through the incision. The entry
10 opening sealing feature includes an inflatable chamber formed between the sleeves to cause the walls of the inner sleeve to contact and form an entrance seal.

Although the devices disclosed in the '921 and '208 patents operate effectively in many applications, improvements are desirable. For example, in
15 the certain applications, the arcuate bands of the exit opening sealing means tend to shift outwardly from the abdomen through the incision thereby adversely affecting the seal. Also, when a surgeon extends a hand through the entrance seal formed by the inner walls of the sleeve, the inner walls may not effectively contact and seal around the entire outer annular surface of the
20 wrist/arm. As a result, an excessive amount of gas is leaked from the patient's body cavity. In addition, improvements in sealing the lower edge of the outer sleeve to prevent leakage would be advantageous.

Therefore, there is a need for an improved access port device for more effectively preventing gas from escaping from the patient's body while allowing the surgeon to effectively operate using minimally invasive surgery techniques.

5

SUMMARY OF THE INVENTION

Therefore, it is an object of the present invention to overcome the disadvantages of the prior art and to provide an access port device capable of permitting effective surgery while permitting body cavity pressure to be easily maintained.

10

It is another object of the present invention to provide an access port device capable of minimizing leakage of gas from the body cavity between the access port device and a surgeon's hand/arm in a simple manner without limiting the movement of the hand.

15

It is yet another object of the present invention is to provide an access port device which effectively prevents inadvertent retraction of a sleeve of the device from a body cavity.

20

Yet another object of the present invention is to provide an access port device capable of creating a gas tight seal between the access port device and patient's body.

Still another object of the present invention is to provide an access port device capable of effectively minimizing gas leakage from a body cavity through the space between the access port device and the patient's body.

A further object of the present invention is to provide an access port device which creates an effective seal without the use of adhesive.

These and other objects of the present invention are achieved by providing an access port device for use in surgery, comprising a first sleeve of flexible material including a proximal end and a distal end, a securing device
5 attached to the distal end of the first sleeve to secure the access port device externally to the patient and a second sleeve of flexible material attached to the proximal end of the first sleeve. The second sleeve includes an entry opening adjacent the proximal end of the first sleeve and an exit opening positioned a
10 spaced distance from the entry opening. An inflatable chamber is formed between the first and second sleeves. The access port device further includes a third sleeve of flexible material attached to at least one of the first and second sleeves wherein the third sleeve includes an annular elastic band positioned between the entry and the exit openings of the second sleeve to sealingly engage
15 a surgeon's arm extending through the third sleeve. The third sleeve is preferably formed of a sufficient length to be positioned adjacent the exit opening and extends along a substantial portion of the second sleeve. Also, the third sleeve may be attached to the second sleeve at a first attachment location adjacent the entry opening and at a second attachment location a spaced distance
20 along the second sleeve from the first attachment location. The elastic band is preferably positioned at a distal end of the third sleeve.

The access port may include an elongated exit opening seal mounted on the second sleeve at the exit opening. The exit opening seal is positioned along

an exit opening seal plane extending through the entry opening and the exit opening of the second sleeve. A second sleeve retraction prevention device may be included for preventing inadvertent retraction of the second sleeve from an incision in a patient's body. The second sleeve retraction prevention device
5 includes at least one transverse wing extending transverse to the exit opening seal plane. The at least one transverse wing includes at least one first wing positioned on a first side of the exit opening and at least one second wing positioned on a second side of the exit opening. Each of the at least one first wings and the at least one second wings may include a pair of wings. The
10 wings may be integrally formed on the elongated exit opening seal. The elongated exit opening seal may include a pair of opposed bands biased together while the transverse wing may be integrally formed on at least one band of the opposed bands. The first pair of wings may be located at a first end of the pair of opposed bands while the second pair of wings is located at a second end of
15 the pair of opposed bands. One wing of each pair of wings extends from the bands in a first transverse direction while the other wing extends from the other band in a second transverse direction opposite to the first direction.

In another embodiment, the access port device of the present invention comprises a sleeve of flexible material including a proximal end and a distal end, and forming an access opening positionable in an incision in a patient's
20 body. The device further includes an outer annular sealing device attached to the proximal end of the sleeve to secure the access port device externally to a patient and an inner annular sealing device attached to the distal end of the

sleeve to secure the access port device internally to the patient. Moreover, the access port device includes an access component removably connected to the outer annular sealing device and including a flexible ring removably engaging the outer annular sealing device. The access component may include an access
5 sleeve of flexible material which may include an integral glove for receiving a surgeon's hand. The access sleeve and glove have a length sufficient to extend from the flexible ring through the access opening. The outer annular sealing device may include an annular groove for receiving the flexible ring and the groove may be formed in an outer peripheral surface of the outer annular
10 sealing device. An inflatable chamber may be formed between the sleeve and the access sleeve. The outer annular sealing device may include a flexible annular extension extending radially inwardly from the outer annular sealing device wherein the annular extension includes an inner annular biasing surface facing outwardly from the patient's body. The annular extension may include
15 a circumferentially unsupported annular floating edge. The device may further include a gas chamber positioned adjacent the inner annular biasing surface to collect gas leaking between the sleeve and the patient's body. Preferably, the flexible annular extension is generally flat. The outer annular sealing device may include an upper annular overhang positioned opposite and spaced from
20 the flexible annular extension so that the gas chamber is positioned between the upper annular overhang and the flexible annular extension. The outer annular sealing device may further include an outer biasing surface facing the inflatable chamber.

Thus, the present invention provides an access port device comprising a first sleeve of flexible material including a proximal end and a distal end and forming an access opening positionable in an incision in a patient's body. The access port device also includes a leakage minimizing feature for minimizing gas leakage from between the first sleeve and the patient's body. The leakage minimizing feature includes an outer annular sealing device attached to the proximal end of the first sleeve, an inner annular sealing device attached to the distal end of the first sleeve for abutting and sealingly engaging an inner surface of a body cavity of the patient, and a seal force applying device for causing leakage gas between the first sleeve and the patient's body to apply a sealing force against the outer annular sealing device to bias the outer annular sealing device toward the patient. The access port device may further include a second sleeve of flexible material positioned adjacent the first sleeve and an inflatable chamber formed between the first and second sleeves. The sealing force applying device may further include the flexible annular extension and the inner biasing surface. The sealing force applying device may further include sizing the first sleeve to fit closely to the patient's cavity wall to cause a sealing force to bias the outer annular sealing device into sealing engagement with the patient's skin. The sealing force applying device may further include the annular overhang, gas chamber and outer biasing surfaces mentioned hereinabove.

The present invention also provides an access port device for use in surgery which comprises a sleeve of flexible material, a nonadhesive outer

annular sealing device attached to a proximal end of the sleeve and adapted to create a nonadhesive, substantially gas tight seal adjacent the patient's body to prevent gas flow from the patient's body and an inner annular sealing device attached to the distal end of the sleeve to secure the access port device
5 internally to the patient. In this case, the access component is sealingly mounted on the outer annular sealing device and extendable into the access opening. The access component may be removably mounted on the outer annular sealing device which may, in turn, include the flexible annular extension.

10

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first embodiment of the access port device of the present invention;

FIG. 2 is a perspective view of the bottom of the first embodiment of FIG. 1;

15 FIG. 3 is a plan view of the opposed bands of the exit opening seal;

FIG. 4 is a perspective view of one of the bands of the exit opening seal;

FIG. 5 is a cross sectional side view of the access port of the first embodiment as applied to a patient prior to access during surgery;

20 FIG. 6 is a cross sectional side view similar to FIG. 5 during use with access by a surgeon's arm;

FIG. 7 is a cross sectional view of a second embodiment of the present invention in use;

FIG. 8 is a cross sectional view of a third embodiment of the present invention including a seal force applying feature; and

5 FIG. 9 is a cross sectional view of the device of FIG. 8 during use but without showing an access component attached.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS 1-6, there is shown a first embodiment of the access port device of the present invention, indicated generally at 10, for permitting
10 access to a patient's body cavity during surgery while maintaining body cavity pressure. Access port device 10 generally includes a first sleeve 12 of flexible material including a proximal end 14 and a distal end 16, a securing device 18 attached to the distal end 16 of first sleeve 12, a second sleeve 20 attached to proximal end 14 of first sleeve 12 and a third sleeve 22 of flexible material
15 attached to at least one of the first sleeve 12 and second sleeve 20. As described hereinbelow, this arrangement can be effectively and sealingly attached to a patient's body surrounding an incision to permit the insertion of a hand into a patient's body cavity while simply and effectively maintaining pneumoperitoneum as desired throughout a laproscopic surgery procedure.

20 Referring to FIGS. 1 and 5, both first sleeve 12 and second sleeve 20 extend annularly with second sleeve 20 positioned inside first sleeve 12.

Second sleeve 20 is preferably integrally formed at proximal end 14 of first sleeve 12, i.e. second sleeve 20 is an integral extension of first sleeve 12 turned inwardly onto itself. Securing device 18 includes a flange 24 extending transversely from distal end 16 for connection to either the patient's skin or wrapping material covering the patient's skin. Preferably, the flange 24 includes an adhesive, such as a solid or a liquid adhesive, for adhering to the wrapping material or skin to securely and sealingly affix the access port device 10 to the patient. Both first sleeve 12 and second sleeve 20 may each be formed from opposing sheets of flexible material fused together along opposite edges 26 and 28, respectively, with edges 26 being positioned outwardly from edges 28. As shown in FIG. 5, an inflatable chamber 30 (FIG. 5) is positioned between first sleeve 12 and second sleeve 20 for receiving pressurized gas via an inlet valve 32 (FIG. 1). Inlet valve 32 is provided on first sleeve 12 so that inflatable chamber 30 can be inflated prior to the insertion of a surgeon's hand into the device as shown in FIG. 5. The gas pressure in inflatable chamber 30 is maintained by gas flowing from the body cavity of the patient during pneumoperitoneum. Thus, after the inflation of chamber 30 through valve 32, valve 32 is closed.

Referring to FIG. 5, the second sleeve 20 forms an entry opening 34 positioned adjacent the proximal end 14 of first sleeve 12 and an exit opening 36 positioned a spaced distance from entry opening 34. Second sleeve 20 has a length sufficient to extend through first sleeve 12 and through an incision 2 formed in a patient's body 4 so as to be positioned in the patient's body cavity

when access port device 10 is applied to the patient as shown in FIG. 5. Access port device 10 further includes an elongated exit opening seal 38 mounted on second sleeve 20 and extending across exit opening 36. Elongated exit opening seal 38 is positioned along an exit opening seal plane, indicated at 40, which extends through entry opening 34 and exit opening 36 of second sleeve 20. Elongated exit opening seal 38 includes a pair of resilient opposed bands 42 as clearly shown in FIGS. 2, 3 and 5. Each band 42 is positioned in a respective elongated cuff 44 formed in the distal end of second sleeve 20. Bands 42 are formed of a resilient flexible material, i.e. plastic, which permits the bands to be flexed outwardly to create an exit opening for receiving a surgeon's hand and/or an instrument. Each of the bands 42 may also include a cushioning strip made from, for example, foam, to provide more comfort to the surgeon's hand/wrist during use. In the relaxed state, the bands 42 are biased together bringing the opposing faces of second sleeve 20 into mutual contact and hence forming an exit opening seal. The geometry of bands 42 is such that, when presented at right angles to the incision 2, it is possible for the bands to pass through the incision. Once in position within the patient's body cavity, bands 42 align themselves nominally parallel to the abdominal wall as shown in FIG. 5. Thus, elongated exit opening seal 38 functions to form an initial seal preventing the escape of gas from the body cavity to the atmosphere via the exit opening 36 of second sleeve 20.

Access port device 10 also includes a second sleeve retraction prevention feature, indicated generally at 46, for preventing inadvertent retraction of

second sleeve 20 from incision 2. It has been found that during use of conventional access port devices, the insufflation pressure in the patient's body cavity acts to undesirably invert the inner sleeve and move the inner sleeve outwardly through the incision. Second sleeve retraction prevention feature 46
5 of the present invention effectively prevents elongated exit opening seal 38, and thus the distal end of second sleeve 20, from passing outwardly through incision 2 under the force of the insufflation pressure. As shown in FIGS. 2-5, second sleeve retraction feature 46 includes at least one transverse wing 48 extending from the distal end of second sleeve 20 transverse to exit opening
10 seal plane 40 (FIG. 5). Specifically, in the preferred embodiment, second sleeve retraction prevention feature 46 includes a transverse wing 48 formed at each end of each of the opposed bands 42 as clearly shown in FIG. 3. Transverse wings 48 are integrally formed on opposed bands 42 and extend transversely generally parallel to the under surface of the patient's body defining the body cavity. The transverse wings 48 extend through respective
15 slits formed in the cuff 44 of second sleeve 20 thereby securing bands 42 within cuff 44. During use, once the distal end of second sleeve 20 has been inserted through incision 2 into the patient's body cavity, transverse wings 48 will prevent inadvertent movement of elongated exit opening seal 38 through
20 incision 2 by abutting the under surface of the patient's body forming the body cavity as shown in FIG. 6. Even prior to insertion of a surgeon's arm into the access port device 10, when insufflation pressure causes movement of exit opening seal 38 toward incision 2, transverse wings 48 will abut the incision

and prevent exit opening seal 38 from passing through incision 2. As a result, second sleeve retraction prevention feature 46 creates a more reliable and effectively usable access port device which can be easily and simply utilized without subsequent repositioning of second sleeve 20 after initial setup.

5 Importantly, access port device 10 of the present invention also includes the third sleeve 22 positioned within, and attached to, second sleeve 20. In the preferred embodiment, third sleeve 22 extends from entry opening 34 of second sleeve 20 to a location adjacent exit opening 36. Third sleeve 22 is attached to, or integrally formed on, second sleeve 20 at a first attachment 50 adjacent entry
10 opening 34. First attachment 50 extends annularly to prevent gas from escaping from the space between second sleeve 20 and third sleeve 22. Third sleeve 22 is also attached to second sleeve 20 at a second attachment 52 located a spaced distance from first attachment 50 along third sleeve 22. Second attachment 52 occurs at a point close to a distal end of third sleeve 22 so as to
15 maintain the distal end in the inner space of second sleeve 20. For example, second attachment 52 may be in the form of two separate weld lines positioned on opposite sides of third sleeve 22. An inflatable gas chamber 60 is formed between second sleeve 20 and third sleeve 22 which captures gas leaking by elongated exit opening seal 38. The inflation of chambers 30 and 60 create an
20 entry opening seal 62 by forcing the opposing surfaces of third sleeve 22 into abutment prior to use as shown in FIG. 5. Thus the combination of exit opening seal 38 and entry opening seal 62 effectively minimizes gas leakage through access port device 10 so as to retain pneumoperitoneum.

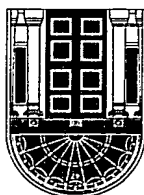
Importantly, third sleeve 22 includes an annular elastic band 54 for sealingly engaging a surgeon's hand, wrist or arm positioned in third sleeve 22 as shown in FIG. 6. In the preferred embodiment, annular elastic band 54 is positioned at the distal end of third sleeve 22. Annular elastic band 54 is sized and designed with sufficient elasticity so as to permit insertion of hands and arms of varying sizes while ensuring a substantially gas tight seal between elastic band 54 and the arm. It will be understood that the size and elasticity of the access port and elastic band 54 can be varied to accommodate, for instance only one finger rather than the entire hand and arm of the surgeon. Also, the size and elasticity of the access port and elastic band 54 may be designed to accommodate instruments of various sizes while still substantially preventing leakage from the patient's body cavity through the access port device 10. It should be noted that the various sleeves of access port device 10 may be manufactured from any flexible, gas impermeable, sterilizable, biocompatible material, for instance polyethylene.

Reference is now made to FIG. 7 which discloses a second embodiment of the present invention directed to an access port device 100 including a first sleeve of flexible material 102 having a proximal end 104 for positioning external to a patient and a distal end 106 for positioning in a patient's body cavity. Access port device 100 includes an outer annular sealing device 110 attached to proximal end 104 of first sleeve 102 and an inner annular sealing device 112 attached to distal end 106 of first sleeve 102. Both outer and inner annular sealing devices 110 and 112 are sized and shaped to extend in an

annular fashion around a given incision and, therefore, may be provided in a variety of sizes depending on the length of the incision. Outer annular sealing device 110 includes a biasing surface 114 facing outwardly away from the patient's body 4. Proximal end 104 of first sleeve 102 is sealingly attached to biasing surface 114 around the entire circumference of outer annular sealing device 110. Likewise, the distal end 106 of first sleeve 102 is sealingly attached to inner annular sealing device 112 in any conventional manner creating a secure sealed connection. Inner annular sealing device 112 may be a ring formed of any flexible, resilient material. Biasing surface 114 is preferably formed on a flexible annular extension 116 of outer annular sealing device 110.

Access port device 100 also includes an access component 118 sealingly engaging outer annular sealing device 110 and extendable into the access opening formed by first sleeve 102. Preferably, access component 118 includes a flexible ring 120 designed for removable mounting in an annular groove 122 formed in outer annular sealing device 110. Flexible ring 120 is preferably formed of an elastic, resilient material to permit the ring to be stretched and moved into groove 122 and, if desired, expanded for removal from groove 122.

Of course, flexible ring 120 is designed with a circumference and sized relative to the size of outer annular sealing device 110 such that stretching of the ring is required for engaging annular groove 122 so that the ring is biased into sealing engagement with outer annular sealing device 110 in annular groove 122. In the present embodiment, access component 118 also includes a sleeve



of flexible material 124 extending from flexible ring 120 and having a length sufficient to extend through the access opening formed by first sleeve 102 and inner annular sealing device 112 as shown in FIG. 7. In the embodiment shown, the sleeve of flexible material 124 may include an integrated glove to
5 form a sleeved glove 126 for receiving a surgeon's hand/arm. As shown in FIG. 7, an inflatable chamber 128 is formed between first sleeve 102 and the sleeve of flexible material 124 for containing gas flowing through the gap between sleeved glove 126 and first sleeve 102 thereby retaining pneumoperitoneum.

10 The first sleeve 102 is sized to permit inner annular sealing device 112 to be effectively positioned underneath the patient's cavity wall 4 and outer annular sealing device 110 to be positioned on the outer surface of the patient while first sleeve 102 fits closely to the patient's cavity wall. As a result, inner
15 annular sealing device 110 is biased tightly against the inner surface of the patient's body cavity wall 4 while first sleeve 102 exerts a downward force on outer annular sealing device 110. In addition, since biasing surface 114 faces outwardly away from the patient's body cavity wall 4, gas pressure in the inflatable chamber creates gas pressure sealing forces acting on biasing surface 114 which tends to bias outer annular sealing device 110 against the patient.
20 Consequently, an effective seal is achieved between outer annular sealing device 110 and the patient's body. Therefore, by sizing first sleeve 102 appropriately and utilizing biasing surface 114, the present access port device 100 creates an effective seal for minimizing gas leakage from the patient's body

cavity through the space between access port device 100 and the patient's body cavity wall 4.

FIGS. 8 and 9 disclose a preferred embodiment of an access port device indicated generally at 150 which is similar to the access port device disclosed in the embodiment of FIG. 7 except for a modified outer annular sealing device 152 which creates a more effective seal against a patient's body in many applications. Similar to the embodiment of FIG. 7, access port device 150 may include an access component (not shown), such as the sleeved glove 126 of the previous embodiment, which can be sealingly mounted in annular groove 154 of outer annular sealing device 152. Also, access port device 150 includes an inner annular sealing device or ring 156 and flexible sleeve 158 forming an access opening 160 similar to the embodiment of FIG. 7. However, in the present embodiment, access port device 150 includes a leakage minimizing device 153 for minimizing gas leakage from between sleeve 158 and the patient's body which includes a sealing force applying feature 159 including outer annular sealing device 152 and a leakage gas chamber 162 for receiving leakage gas leaking between access port device 150 and the patient. In addition, outer annular sealing device 152 includes a flexible annular extension 164 having a generally flat shape and extending radially inwardly to form a circumferentially unsupported annular floating edge 166. Flexible annular extension 164 also includes an inner biasing surface 168 facing outwardly from the patient and exposed to gas in the gas chamber 162. The outer annular sealing device 152 further includes an overhang 170 which in part forms gas

chamber 162 and includes an outer biasing surface 172. The sleeve 158 is sealingly attached to outer biasing surface 172. Therefore, gas chamber 162 is formed between flexible annular extension 164 and overhang 170. It should be noted that overhang 170 may be designed with a sufficient length so as to
5 abut the patient's skin when placed on the patient as shown in FIG. 9.

When applied to a patient's body as shown in FIG. 9, the sealing force applying feature 159 effectively minimizes leakage between access port device 150 and the patient's body in the following manner. When the device is attached to the patient, inner annular sealing device 156 lies tight against the
10 inner surface of the patient's body cavity, i.e. abdomen. The flexible sleeve 158 is sized, as discussed hereinabove with respect to the embodiment of FIG. 7, so as to exert a downward force on outer annular sealing device 152 causing compression of flexible annular extension 164 against the patient's skin or an intermediate material. The access component of FIG. 7 may then be attached
15 to annular groove 154 by stretching flexible ring 120 around outer annular sealing device 152 so as to position ring 120 in groove 154. If the access component is in the form of sleeved glove 126, the surgeon would place the glove on his hand by inserting his arm into the sleeved glove prior to mounting the access component on outer annular sealing device 152. After placing the
20 glove on his hand, flexible ring 120 would then be placed in annular groove 154 while the surgeon's arm is extended through access opening 160. Also, before attaching the sleeve glove 126 to outer annular sealing device 152, the overall length of the sleeve glove 126 may be adjusted by rolling or unrolling

the flexible ring 120 to thereby take-up or release the flexible material from ring 120.

During use, with the patient's body cavity deliberately pressurized by introducing gas as shown in FIG. 9, any leakage gas from the patient's body cavity, leaking between inner annular sealing device 156 and the patient, will flow in the space between sleeve 158 and the patient toward gas chamber 162. This leakage gas will be trapped in gas chamber 162. Gas pressure induced biasing forces are then generated on inner biasing surface 168 so as to bias flexible annular extension 164 into sealing abutment against the patient's skin thereby creating an enhanced seal between flexible annular extension 164 and the patient. The greater the gas pressure in gas chamber 162, the greater the sealing force between flexible annular extension 164 and the patient's skin. As a result, increased leakage into gas chamber 162 not only maintains but tends to enhance the seal between outer annular sealing device 152 and the patient's skin. In the event flexible annular extension 164 lifts away from the patient's skin, inner annular sealing device 156 will remain in contact with the patient's skin thereby maintaining a seal. Also, the gas pressure in the inflatable chamber formed between sleeve 158 and the access component imparts gas pressure induced forces on outer biasing surface 172 tending to bias overhang 170 into abutment with the patient's skin thereby further assisting in sealing against leakage. When it is desired to remove the sleeved glove 126, the surgeon's hand may simply be pulled outwardly and removed from sleeved glove 126 or the flexible ring 120 may be first released from outer annular

sealing devices 110, 152. Preferably, the seal created between outer annular sealing device 110 due to the effect of leakage minimizing device 153 is sufficient to avoid the use of adhesive between device 153 and the patient, thereby creating a nonadhesive sealed access port. If an adhesive is used,
5 which is more likely in the embodiment of FIG. 7, a liquid adhesive may be applied.

I claim:

1. An access port device for use in surgery, comprising:
a first sleeve of flexible material including a proximal end and a
distal end;
5 a securing device attached to said distal end of said first sleeve to
secure the access port device externally to a patient;
a second sleeve of flexible material attached to the proximal end
of said first sleeve, said second sleeve including an entry opening adjacent said
proximal end of said first sleeve and an exit opening positioned a spaced
10 distance from said entry opening;
an inflatable chamber formed between said first and said second
sleeves;
a third sleeve of flexible material attached to at least one of said
first sleeve and said second sleeve, said third sleeve including an annular elastic
15 band positioned between said entry and said exit openings of said second
sleeve to sealingly engage a surgeon's arm extending through said third sleeve.
2. The access port device of claim 1, wherein said third sleeve is of
a sufficient length to be positioned adjacent said exit opening.
3. The access port device of claim 2, wherein said third sleeve
20 extends along a substantial portion of said second sleeve.

4. The access port device of claim 3, wherein said third sleeve is attached to said second sleeve at a first attachment location adjacent said entry opening and at a second attachment location a spaced distance along said second sleeve from said first attachment location.

5 5. The access port device of claim 1, wherein said elastic band is positioned at a distal end of said third sleeve.

6. An access port device for use in surgery, comprising:
a first sleeve of flexible material including a proximal end and a distal end;

10 a securing device attached to said distal end of said first sleeve to secure the access port externally to a patient;

a second sleeve of flexible material attached to the proximal end of said first sleeve, said second sleeve including an entry opening adjacent said proximal end of said first sleeve and an exit opening positioned a spaced distance from said entry opening for insertion into an incision formed in a patient's body;

an inflatable chamber formed between said first and said second sleeves;

20 an elongated exit opening seal mounted on said second sleeve at said exit opening, said exit opening seal positioned along an exit opening seal

plane extending through said entry opening and said exit opening of said second sleeve;

5 a second sleeve retraction prevention means for preventing inadvertent retraction of said second sleeve from the incision, said second sleeve retraction prevention means including at least one transverse wing extending transverse to said exit opening seal plane.

10 7. The access port device of claim 6, wherein said at least one transverse wing includes at least one first wing positioned on a first side of said exit opening and at least one second wing positioned on a second side of said exit opening.

8. The access port device of claim 7, wherein each of said at least one first wing and said at least one second wing includes a pair of wings.

9. The access port device of claim 6, wherein said at least one transverse wing is integrally formed on said elongated exit opening seal.

15 10. The access port device of claim 6, wherein said elongated exit opening seal includes a pair of opposed bands biased together, said at least one transverse wing integrally formed on at least one band of said pair of opposed bands.

11. The access port device of claim 10, wherein said at least one transverse wing includes a first pair of wings and a second pair of wings.

12. The access port device of claim 11, wherein said first pair of wings is located at a first end of said pair of opposed bands and said second pair of wings is located at a second end of said pair of opposed bands.

13. The access port device of claim 12, wherein one wing of said first pair and one wing of said second pair of wings extend from one band of said pair of opposed bands in a first transverse direction and the other wing of said first pair and the other wing of said second pair of wings extend from the other band in a second transverse direction opposite said first transverse direction.

14. An access port device for use in surgery, comprising:
a sleeve of flexible material including a proximal end and a distal end, and forming an access opening positionable in an incision in a patient's body;

an outer annular sealing device attached to said proximal end of said sleeve to secure the access port device externally to a patient;

an inner annular sealing device attached to said distal end of said sleeve to secure the access port device internally to the patient;

an access component removably connected to said outer annular sealing device, said access component including a flexible ring removably engaging said outer annular sealing device.

5 15. The access port device of claim 14, wherein said access component includes a sleeved glove.

10 16. The access port device of claim 14, wherein said access component includes an access sleeve of flexible material, said access sleeve including an integral glove for receiving a surgeon's hand, said access sleeve and glove having a length sufficient to extend from said flexible ring through said access opening.

17. The access port device of claim 14, wherein said outer annular sealing device includes an annular groove for receiving said flexible ring.

18. The access port device of claim 17, wherein said annular groove is formed in an outer peripheral surface of said outer annular sealing device.

15 19. The access port device of claim 14, wherein said access component further includes an access sleeve of flexible material positioned adjacent to said sleeve, the device further including an inflatable chamber formed between said sleeve and said access sleeve.

20. The access port device of claim 19, wherein said outer annular sealing device further includes a flexible annular extension extending radially inwardly from said outer annular sealing device, said annular extension including a inner annular biasing surface facing outwardly from the patient's
5 body.

21. The access port device of claim 20, wherein said annular extension includes a circumferentially unsupported annular floating edge.

22. The access port device of claim 20, further including a gas chamber positioned adjacent said inner annular biasing surface to collect gas
10 leaking between said sleeve and the patient's body.

23. The access port device of claim 22, wherein said flexible annular extension is generally flat.

24. The access port device of claim 22, wherein said outer annular sealing device includes an upper annular overhang positioned opposite and
15 spaced from said flexible annular extension, said gas chamber being positioned between said upper annular overhang and said flexible annular extension.

25. The access port device of claim 20, said outer annular sealing device further including an outer biasing surface facing said inflatable chamber

to cause gas pressure in said inflatable chamber to apply a gas pressure sealing force against said outer biasing surface to bias said outer annular sealing device into abutment with the patient's outer surface.

26. An access port device for use in surgery, comprising:

5 a first sleeve of flexible material including a proximal end and a distal end, and forming an access opening positionable in an incision in a patient's body; and

a leakage minimizing means for minimizing gas leakage from between said first sleeve and the patient's body; said leakage minimizing means
10 including an outer annular sealing device attached to said proximal end of said first sleeve, an inner annular sealing device attached to said distal end of said first sleeve for abutting and sealingly engaging an inner surface of a body cavity of the patient, and a sealing force applying means for causing leakage
15 against said outer annular sealing device to bias said outer annular sealing device toward the patient.

27. The access port device of claim 26, further including a second sleeve of flexible material positioned adjacent to said first sleeve and an inflatable chamber formed between said first sleeve and said second sleeve.

28. The access port device of claim 27, wherein said sealing force applying means includes a flexible annular extension extending radially inwardly from said outer annular sealing device and an inner biasing surface facing outwardly away from the patient's body.

5 29. The access port device of claim 28, wherein said annular extension includes a circumferentially unsupported annular floating edge.

10 30. The access port device of claim 26, wherein said sealing force applying means further includes a leakage gas chamber means positioned adjacent said outer annular sealing device for collecting gas leakage between said first sleeve and the patient's body.

 31. The access port device of claim 28, wherein said sealing force applying means further includes a gas chamber positioned adjacent said inner biasing surface to collect gas leaking between said first sleeve and the patient's body.

15 32. The access port device of claim 31, wherein said flexible annular extension is generally flat.

 33. The access port device of claim 32, wherein said outer annular ring includes an upper annular overhang positioned opposite and spaced from

said flexible annular extension, said gas chamber being positioned between said upper annular overhang and said flexible annular extension.

34. The access port device of claim 26, wherein said leakage minimizing means includes sizing said first sleeve to fit closely to the patient's cavity wall to cause a sealing force to bias said outer annular sealing device into sealing engagement with the patient's skin.

35. The access port device of claim 33, wherein sealing force applying means further includes an outer biasing surface formed on said overhang and adapted to receive gas pressure biasing forces tending to bias said overhang into abutment with the patient's outer surface.

36. An access port device for use in surgery, comprising:
a sleeve of flexible material including a proximal end and a distal end, and forming an access opening positionable in an incision in a patient's body;
a nonadhesive outer annular sealing device attached to said proximal end of said sleeve and adapted to create a nonadhesive, substantially gas-tight seal adjacent the patient's body to prevent gas flow from the patient's body;

an inner annular sealing device attached to said distal end of said sleeve to secure the access port device internally to the patient; and

an access component sealingly mounted on said outer annular sealing device and extendable into said access opening.

5 37. The access port device of claim 36, wherein said access component is removably mounted on said outer annular sealing device.

10 38. The access port device of claim 37, wherein said nonadhesive outer annular sealing device includes a flexible annular extension extending radially inwardly and an inner biasing surface formed on said flexible annular extension and facing outwardly away from the patient's body.

 39. The access port device of claim 38, wherein said annular extension includes a circumferentially unsupported annular floating edge.

15 40. The access port device of claim 38, further including a gas chamber positioned adjacent said inner biasing surface to collect gas leaking between said sleeve and the patient's body.

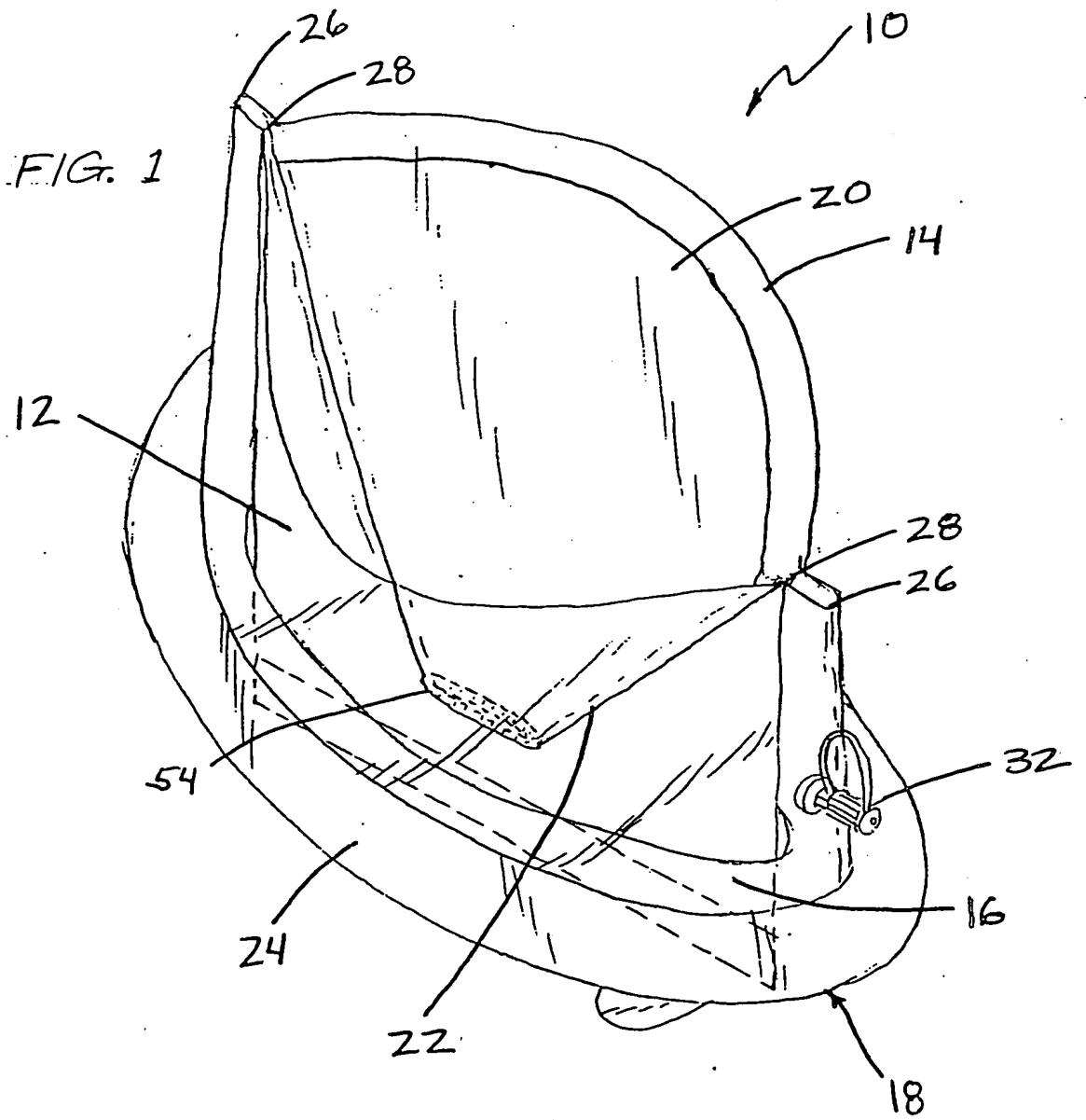
 41. The access port device of claim 37, wherein said flexible annular extension is generally flat.

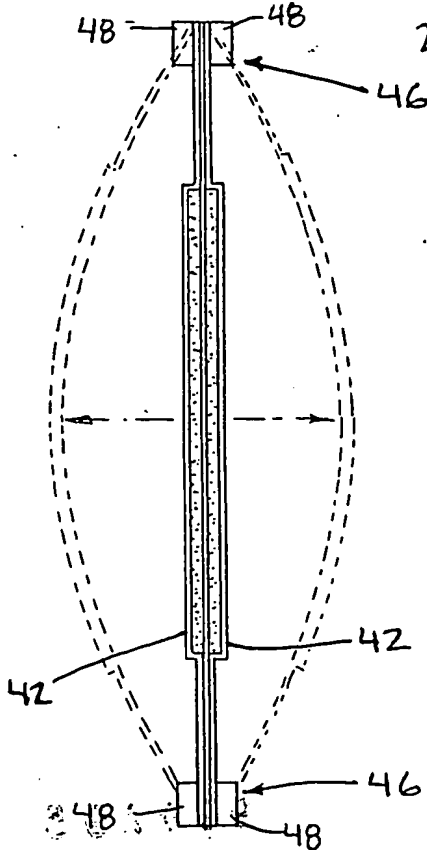
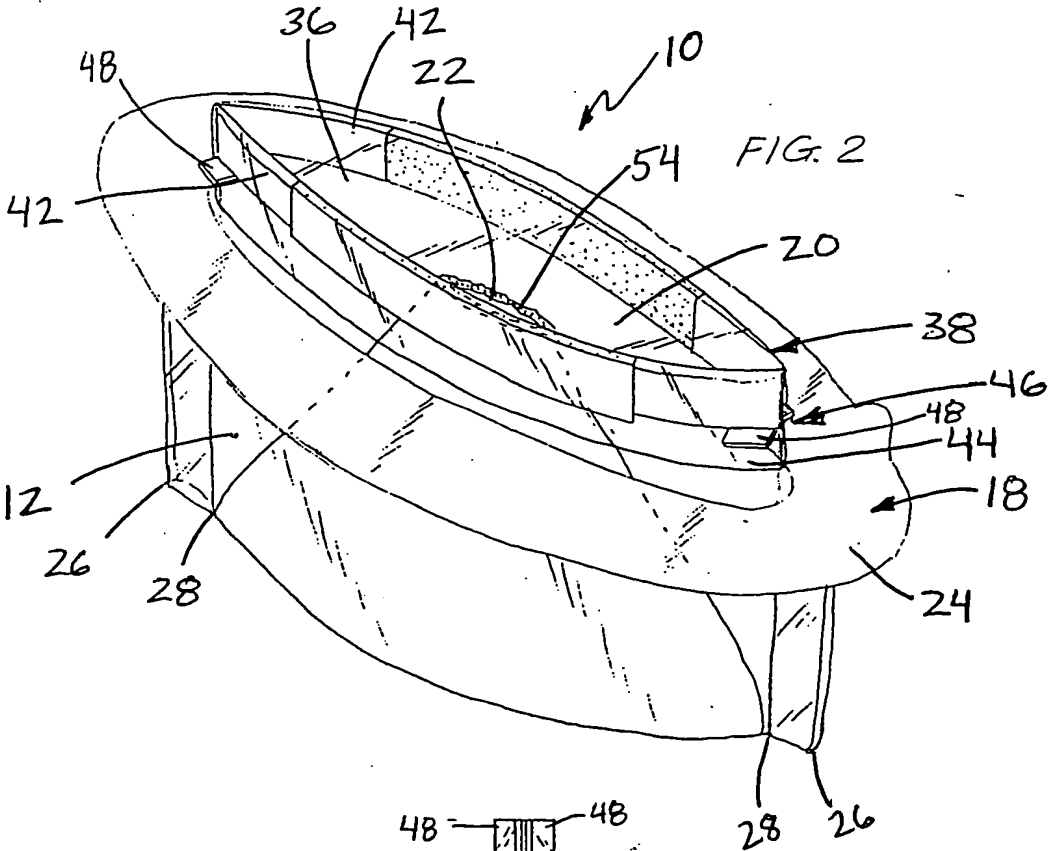
42. A hand access substantially in accordance with either of the embodiments as herein described with reference to and as shown in the accompanying drawings.

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FIG. 1





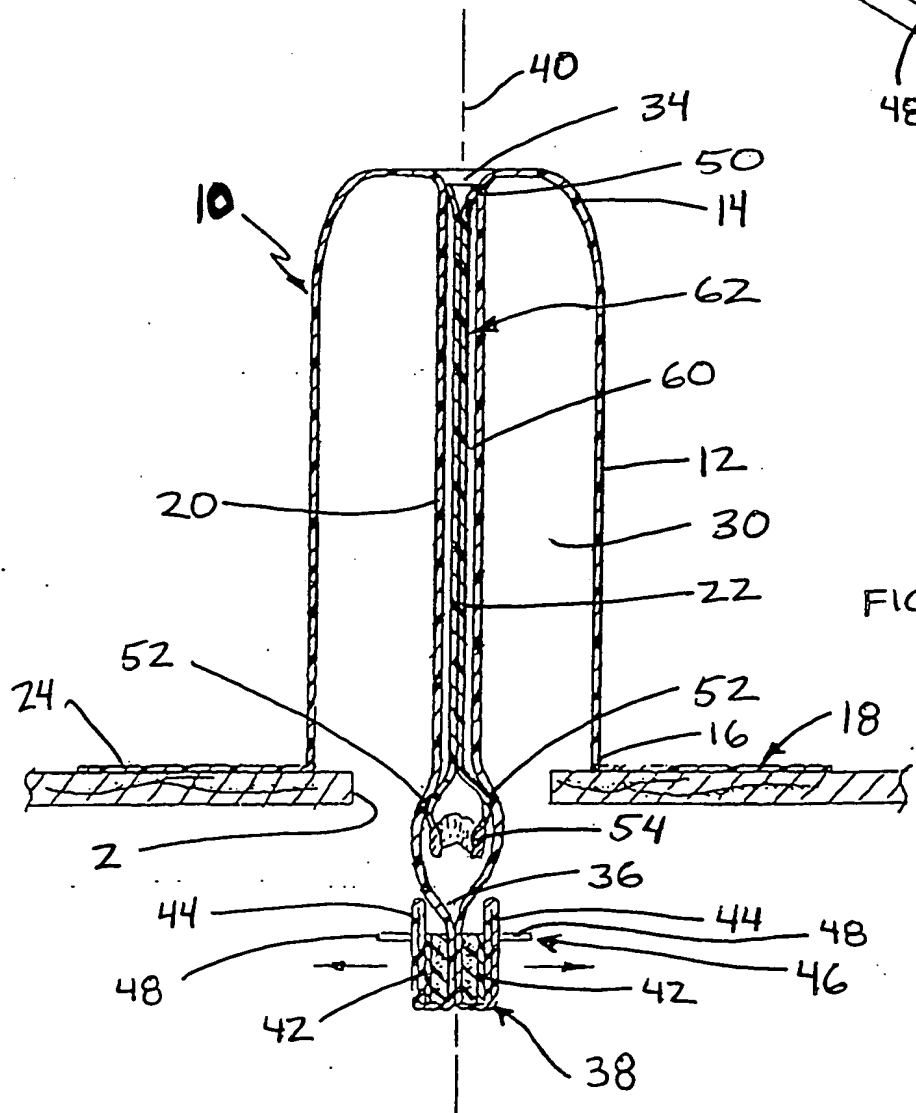
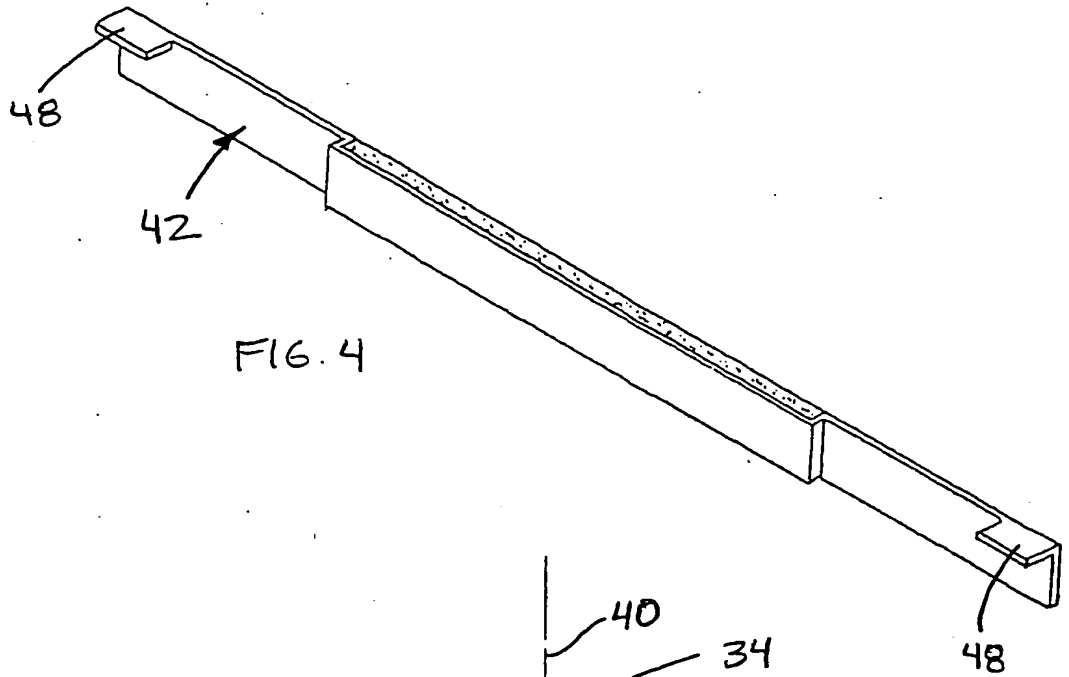
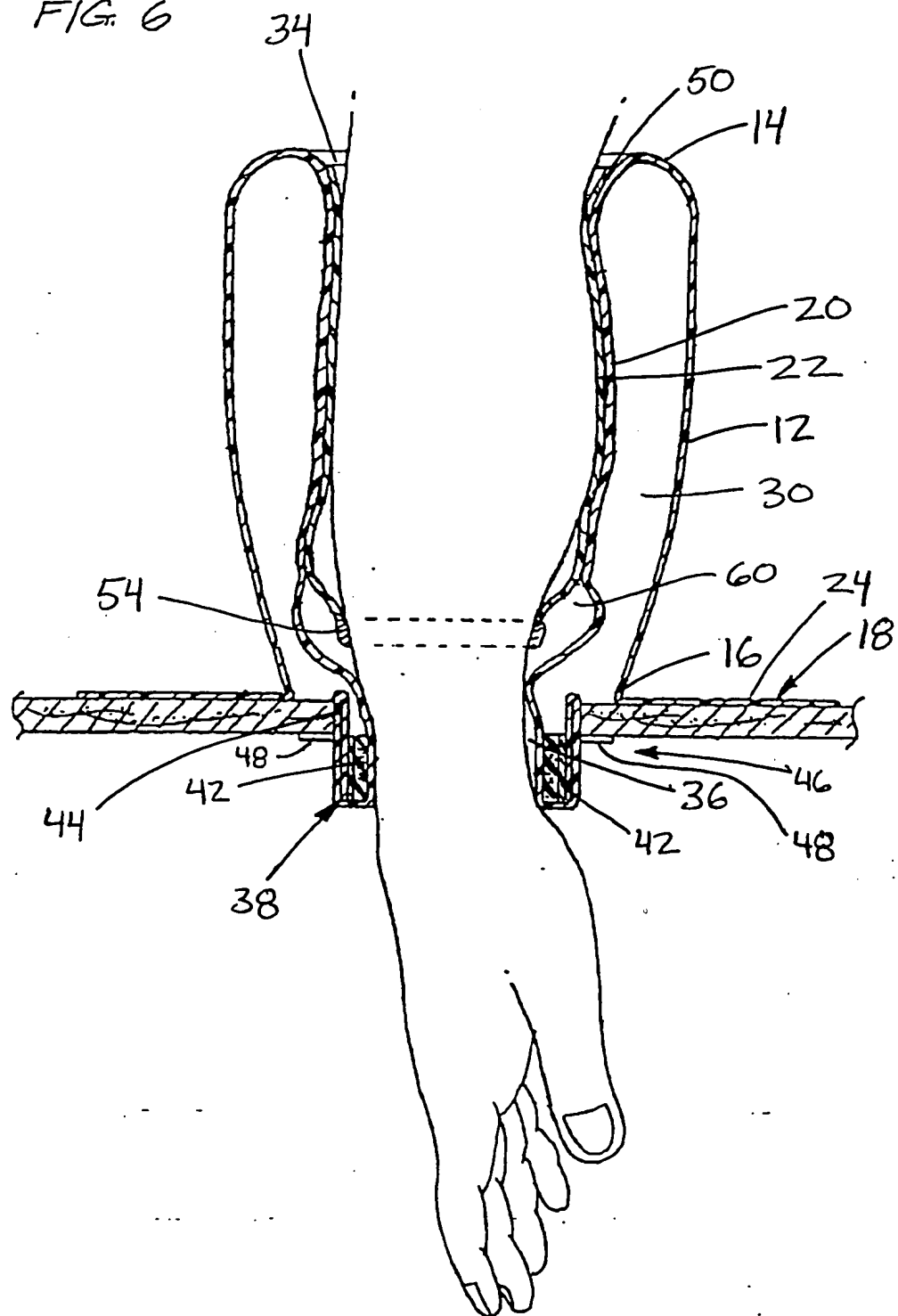


FIG. 6



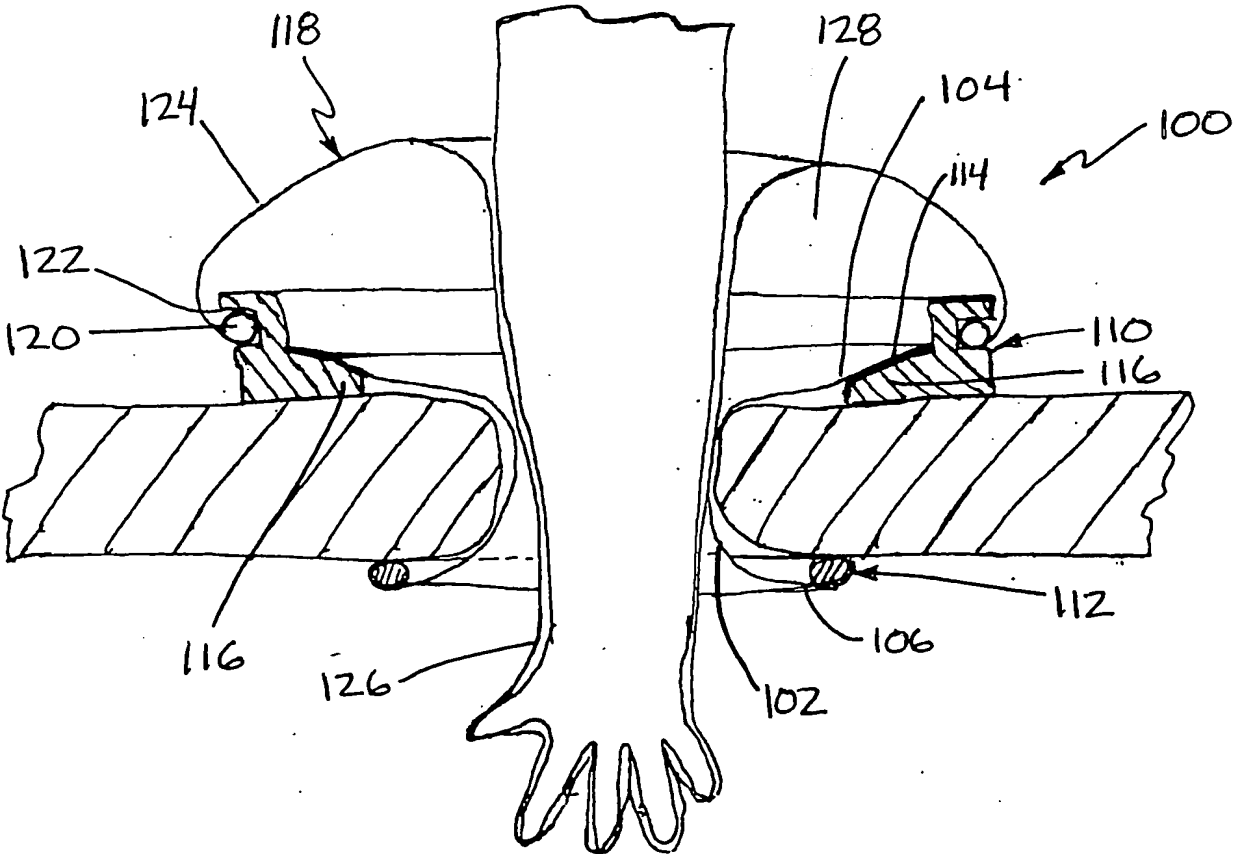


FIG. 7

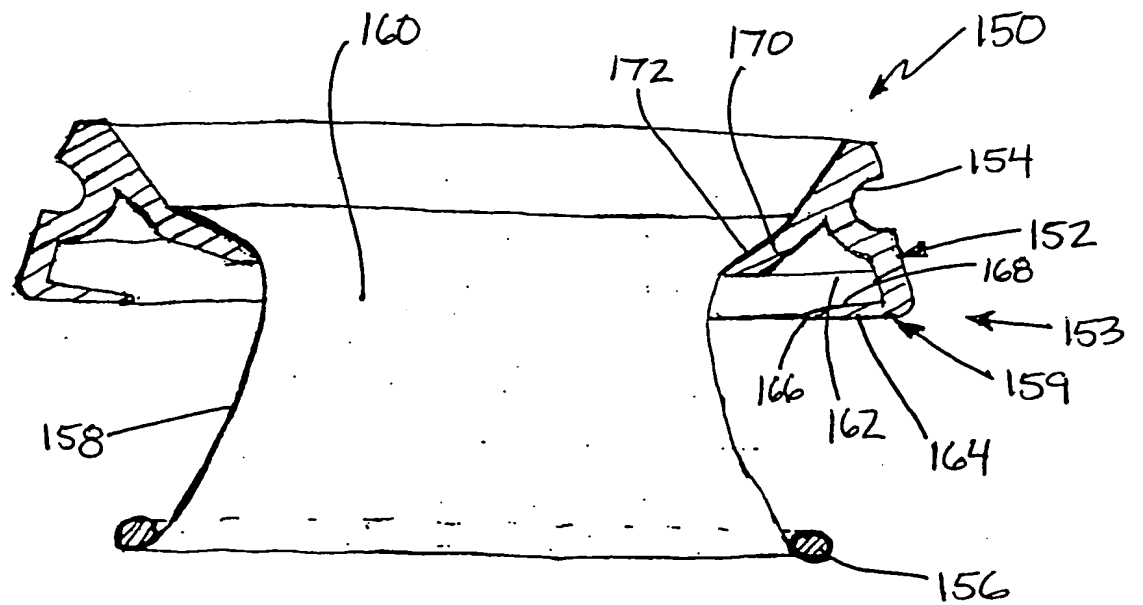


FIG. 8

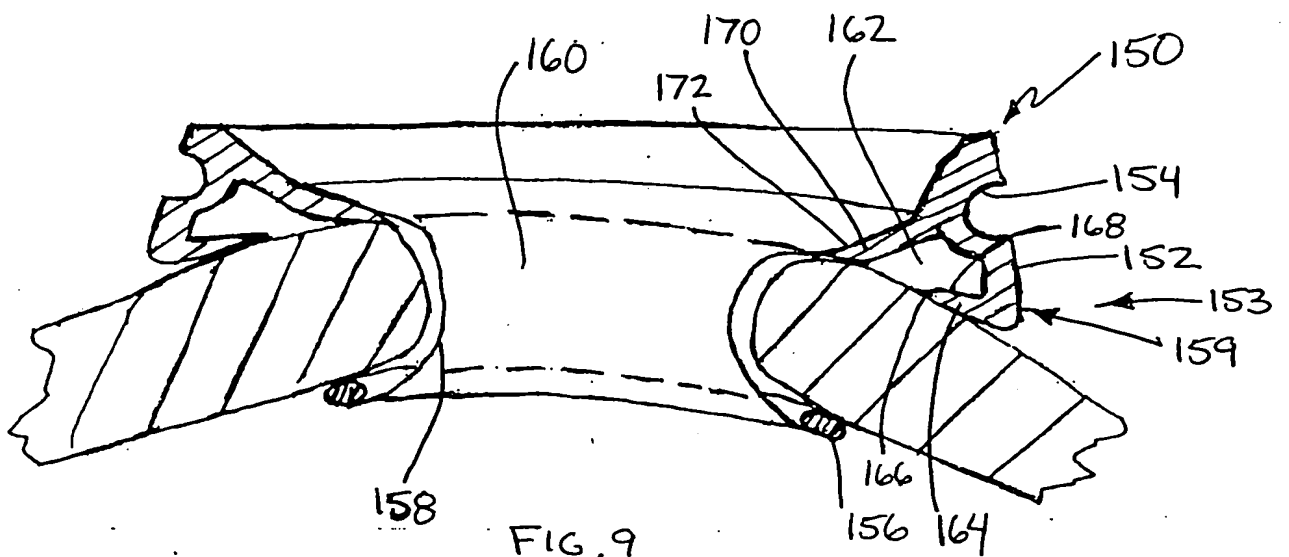


FIG. 9